UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 21, 2007

MEMORANDUM

Subject: Efficacy Review for Maquat 710-HF, EPA Reg. No. 10324-159; DP Barcode: D340122

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
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Thru: Tajah Blackburn, Acting Team Leader
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8/21/07

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble / Tracy Lantz
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Mason Chemical Company
721 W. Algonquin Road
Arlington Heights, IL 60005

Formulation from the Label:

Active Ingredient(s)	% by wt.
Octyl Decyl Dimethyl Ammonium Chloride	3.0 %
Didecyl Dimethyl Ammonium Chloride	1.5 %
Dioctyl Dimethyl Ammonium Chloride	1.5 %
Alkyl (C_{14}, 50%, C_{12}, 40%; C_{16}, 10%) dimethyl benzyl ammonium chloride	4.0 %
Other Ingredients	90.0 %
Total	100.0 %

I. BACKGROUND

The product, Maquat 710-HF (EPA Reg. No. 10324-159), is an EPA-approved disinfectant, deodorizer, and non-food contact sanitizer for use on hard, non-porous surfaces in institutional, household, commercial, and hospital or medical environments. The applicant requested an amendment to the registration of this product to modify the use directions to include application of the product through a foam generating machine and expand the uses to include floor drains in food processing facilities. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated May 11, 2007), EPA Form 8570-4 (Confidential Statement of Formula), fourteen studies (MRID Nos. 471264-01, 471264-02, 471264-03, 471264-05 through 471264-14, and 471393-01), Statements of No Data Confidentiality Claims for all fourteen studies, and the proposed label.

II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as counter tops, stove tops, sinks, exterior surfaces of appliances, refrigerators and ice machines, non-food contact equipment, shelves, racks, carts, plumbing fixtures, tables, chairs, desks, bed frames, floors, walls, cabinets, doorknobs, garbage cans, picnic tables and outdoor furniture, telephones, showers, bathtubs, toilets, urinals, and kennels. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare a use solution by adding 1 ounce of the product to 1 gallon of water (a 1:128 dilution). Apply the use solution using a cloth, mop, or mechanical spray device. Allow surfaces to remain wet for 10 minutes. Allow to air dry. For heavily soiled areas, a preliminary cleaning is required. Rinse food contact surfaces with potable water prior to reuse.

The product also is designed to be used for sanitizing hard, non-porous, non-food contact surfaces such as walls, floors, and tables. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer: Pre-clean surfaces. Prepare a use solution by adding 1 ounce of the product to 4 gallons of water (a 1:512 dilution). Apply the use solution using a cloth, mop, sponge, or spray foam generator, or by immersion. Allow surfaces to remain wet for 1 minute. Wipe dry or allow to air dry.

The foam generated from this product can be used for sanitizing hard, non-porous, non-food contact surfaces and floor drains in food processing facilities. Directions on the proposed label provided the following information regarding preparation and use of the product as a foam sanitizer: Pre-clean surfaces. Prepare a use solution by adding 2 ounces of the product to 4 gallons of water (a 1:256 dilution). Apply or shout foam using foam generator for at least 10 seconds or longer. Allow 5 minutes minimum contact time. Rinse surfaces thoroughly and allow to air dry. Drains can be returned to service with or without rinsing.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-10 may be used. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load,

such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 471393-01 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Listeria monocytogenes* (ATCC 19117)" for Maquat 710-HF, by Becky Lien. Study conducted at ATS Labs. Study completion date – March 23, 2007. Project Number A04537.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). One lot (Lot No. 1621-240) of the product, Maquat 710-HF, was tested according to ATS Labs Protocol No. MC03110906.NFS. A use solution was prepared by adding 1.0 mL of the product to 255.0 mL of filter sterilized deionized water (a 1:256 dilution). Fetal bovine serum was added to the culture to achieve a 50% organic soil load. Five (5) glass carriers were inoculated with 0.02 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 30 minutes at roughly 35-37°C and a relative humidity of 40%. The carriers were sprayed at room temperature (22°C) until covered in test substance foam and immediately placed upright at 45°-90° angle for five minutes. After exposure, carriers were placed, individually, in jars containing 20.0 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80, to neutralize. The jars were rotated vigorously

on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10^0 and 10^{-1} dilutions of the neutralizer solution from each of the jars were plated in duplicate on Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for approximately 46 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Listeria monocytogenes* 3.0 x 10^5.**

2. MRID 471264-01 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Enterobacter aerogenes* (ATCC 13048)" for Maquat 710-HF, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – August 17, 2006. Project Number A04122.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 1621-232, 1621-240, and 1621-241) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03072006.NFS. A use solution was prepared by adding 1.0 mL of the product to 255.0 mL of filter sterilized deionized water (a 1:256 dilution). The lot 1621-232 was at least 60 days hold. Fetal bovine serum was added to the culture to achieve a 50% organic soil load. Fifteen (15) glass carriers, five per product lot, were inoculated with 0.02 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at 36.1°C and a relative humidity of 40%. The carriers were sprayed at room temperature (22°C) until covered in test substance foam. After 5 minutes exposure time, carriers were placed, individually, in jars containing 20.0 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80, to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10^0 and 10^{-1} dilutions of the neutralizer solution from each of the jars were plated in duplicate on Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 20-30°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Enterobacter aerogenes* 5.28 x 10^6.**

3. MRID 471264-02 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Listeria monocytogenes* (ATCC 19117)" for Maquat 710-HF, by Becky Lien. Study conducted at ATS Labs. Study completion date – October 17, 2006. Project Number A04370.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot Nos. 1621-240, and 1621-241) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03097206.NFS.2. A use solution was prepared by adding 1.0 mL of the product to 255.0 mL of filter sterilized deionized water (a 1:256 dilution). Fetal bovine serum was added to the culture to achieve a 50% organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.02 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at roughly 35-37°C and a relative humidity of 40%. The carriers were sprayed at room temperature (21°C) until covered in test substance foam. After 5 minutes exposure time, carriers were placed, individually, in jars containing 20.0 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80, to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the

neutralizer, 1.0 mL of the 10^0 and 10^{-1} dilutions of the neutralizer solution from each of the jars were plated in duplicate on Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 20-30°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Listeria monocytogenes*** **2.0 x 10^6.**

4. MRID 471264-03 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maquat 710-HF, by Becky Lien. Study conducted at ATS Labs. Study completion date – October 17, 2006. Project Number A04363.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 1621-232, 1621-240, and 1621-241) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03092706.NFS.1. A use solution was prepared by adding 1.0 mL of the product to 255.0 mL of filter sterilized deionized water (a 1:256 dilution). The lot 1621-232 was at least 60 days hold. Fetal bovine serum was added to the culture to achieve a 50% organic soil load. Fifteen (15) glass carriers, five per product lot, were inoculated with 0.02 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at 36.1°C and a relative humidity of 40%. The carriers were sprayed at room temperature (21°C) until covered in test substance foam. After 5 minutes exposure time, carriers were placed, individually, in jars containing 20.0 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80, to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10^0 and 10^{-1} dilutions of the neutralizer solution from each of the jars were plated in duplicate on Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 20-30°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Staphylococcus aureus*** **1.7 x 10^6.**

5. MRID 471264-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – April 2, 2007. Project Number A04759.

This study was conducted against Newcastle disease virus, Strain B1, Hitchner or Blacksburg (ATCC VR-108), using cultures of chicken embryo fibroblast (CEF; obtained from Charles River SPAFAS) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.NEW. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in

Minimum Essential Medium (MEM) supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 2.0 mM L-glutamine, and 5% tryptose phosphate broth. CEF cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **3.5 $\log_{10}$** for both batches.

6. MRID 471264-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – March 23, 2007. Project Number A04758.

This study was conducted against Porcine Respiratory & Reproductive Syndrome virus (PRRS), Strain NVSL (obtained from the University of Kentucky), using MARC-145 cells (obtained from National Veterinary Services Laboratories, Ames, Iowa) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.PRRS. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MARC-145 cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **5.0 $\log_{10}$** for both batches.

7. MRID 471264-07 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 21, 2007. Project Number A04753.

This study was conducted against Porcine Rotavirus, Strain OSU (ATCC VR-893), using Rhesus monkey kidney cells (MA-104, obtained from Diagnostic Hybrids, Inc., Athens, OH) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.PROT. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity

of 51% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 0.5 µg/ml trypsin, 2.0 mM L-glutamine, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MA-104 cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **7.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **7.0 $\log_{10}$** for both batches.

8. MRID 471264-08 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Karen M. Ramm. Study conducted at ATS Labs. Study completion date –April 4, 2007. Project Number A04763.

This study was conducted against Avian Influenza A (H3N2) virus (Avian Reassortant), Strain A/Washington/897/80 X A/Mallard/New York/6750/78 (ATCC VR-2072), using Rhesus monkey kidney (RMK) cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Three lots (Lot Nos. 1621-232, 1621-240, and 1621-241) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.AFLU. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.1°C in a relative humidity of 42% until visibly dry (20 minutes). For each lot of product, five separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. RMK cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The average titer of the dried virus control was **5.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.5 $\log_{10}$** for all three batches.

9. MRID 471264-09 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 29, 2007. Project Number A04756.

This study was conducted against Avian Reovirus, Strain 2177 (ATCC VR-2449), using cultures of chicken embryo fibroblast cells (CEF; obtained from Charles River SPAFAS) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.AREO. A use solution was prepared by

adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 42% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 2.0 mM L-glutamine, and 5% tryptose phosphate broth. CEF cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **4.0 $\log_{10}$** for both batches.

10. MRID 471264-10 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – April 3, 2007. Project Number A04761.

This study was conducted against Infectious Laryngotracheitis, Strain LT-IVAX (obtained from the Poultry Health and Specialties, St Cloud, MN), using cultures of chicken embryo liver cells (CEL; obtained from Charles River SPAFAS) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.ILGT. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (lamb serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 52% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated lamb serum, 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 2.0 mM L-glutamine, and 5% tryptose phosphate broth. CEL cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.75 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **4.25 $\log_{10}$** for both batches.

11. MRID 471264-11 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Mary J. Miller. Study conducted at ATS Labs. Study completion date – April 3, 2007. Project Number A04757.

This study was conducted against Avian Adenovirus, Strain Fontes (ATCC VR-280), using cultures of chicken embryo fibroblast cells (CEF; obtained from Charles River SPAFAS) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.AADV. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 45% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 2.0 mM L-glutamine, and 5% tryptose phosphate broth. CEF cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **3.0 $\log_{10}$** for both batches.

12. MRID 471264-12 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 28, 2007. Project Number A04755.

This study was conducted against Vesicular Stomatitis, Strain Indiana (ATCC VR-158), using cultures of LLC-MK_2 cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.VSTV. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. LLC-MK_2 cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **7.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **7.0 $\log_{10}$** for both batches.

13. MRID 471264-13 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 28, 2007. Project Number A04754.

This study was conducted against Pseudorabies, Strain Aujeszky (ATCC VR-135), using cultures of feline kidney cells (CRFK; ATCC CCL-94) as the host system. Two lots (1621-232 and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.PSRV. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C in a relative humidity of 50% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. CRFK cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was at least **5.5 $\log_{10}$** for both batches.

14. MRID 471264-14 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – April 3, 2007. Project Number A04762.

This study was conducted against Swine Influenza A, Strain A/Swine/Iowa/15/30 (ATCC VR-333), using Rhesus monkey kidney (RMK) cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) as the host system. Two lots (Lot Nos. 1621-232, and 1621-240) of the product, Maquat 710-HF, were tested according to ATS Labs Protocol No. MC03022807.SFLU. A use solution was prepared by adding 1.0 mL of the product to 127.0 mL of filter sterilized deionized water (a 1:128 dilution; 781 ppm). The stock virus culture contained a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.1°C in a relative humidity of 48% until visibly dry (20 minutes). For each lot of product, separate dried virus films were exposed to 2.0 ml of the use dilution of the product for ten minutes at 20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. RMK cells in sterile multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The average titer of the dried virus control was **6.75 $\log_{10}$**. Taking the cytotoxicity and

neutralization control results into consideration, the reduction in viral titer was **6.25 log_{10}** for all three batches.

V. RESULTS

MRID Number	Organism	Lot No.	Average No. Surviving (CFU/carrier)	Microbes Initially Present (CFU/carrier)	Percent Reduction
471264-01	*Enterobacter aerogenes*	1621-232	$<2 \times 10^1$	5.28×10^6	>99.9%
		1621-240	$<2 \times 10^1$	5.28×10^6	>99.9%
		1621-241	$<2 \times 10^1$	5.28×10^6	>99.9%
471264-03	*Staphylococcus aureus*	1621-232	$<2 \times 10^1$	1.7×10^6	>99.9%
		1621-240	$<2 \times 10^1$	1.7×10^6	>99.9%
		1621-241	$<2 \times 10^1$	1.7×10^6	>99.9%
471264-02	*Listeria monocytogenes*	1621-240	$<2 \times 10^1$	2.0×10^6	>99.9%
		1621-241	$<2 \times 10^1$	2.0×10^6	>99.9%
471393-01	*Listeria monocytogenes*	1621-240	$<2 \times 10^1$	3.0×10^5	>99.9%

MRID Number	Organism	Results	Lot No. 1621-232	Lot No. 1621-240	Dried Virus Control ($TCID_{50}$/0.1 ml)
471264-05	Newcastle disease virus	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{5.0}$
		10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		TCD_{50}/0.1ml	$10^{1.5}$	$10^{1.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 3.5 log_{10}	≥ 3.5 log_{10}	
471264-06	Respiratory & Reproductive Syndrome virus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥ 5.0 log_{10}	≥ 5.0 log_{10}	
471264-07	Porcine Rotavirus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{7.5}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

		Log reduction	≥7.0 $\log_{10}$	≥7.0 $\log_{10}$	
71264-09	Avian Reovirus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥4.0 $\log_{10}$	≥4.0 $\log_{10}$	
471264-10	Infectious Laryngotracheitis	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥4.25 $\log_{10}$	≥4.25 $\log_{10}$	
471264-11	Avian Adenovirus	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{4.5}$
		10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		TCD_{50}/0.1ml	$10^{1.5}$	$10^{1.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥3.0 $\log_{10}$	≥3.0 $\log_{10}$	
71264-12	Vesicular Stomatitis	10^{-1} to 10^{-9} dilutions	Complete inactivation	Complete inactivation	$10^{7.5}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥7.0 $\log_{10}$	≥7.0 $\log_{10}$	
471264-13	Pseudorabies	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.0}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥5.5 $\log_{10}$	≥5.5 $\log_{10}$	
471264-14	Swine Influenza A	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{6.75}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥6.25 $\log_{10}$	≥6.25 $\log_{10}$	

MRID No.	**Organism**	**Results**				**Plate Recovery Control**
			Lot No. 1621-232	**Lot No. 1621-240**	**Lot No. 1621-241**	
471264-08	Avian Influenza A virus	10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	Complete inactivation	($TCID_{50}$/0.1 ml) $10^{4.5}$
		TCD_{50}/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		$TCID_{50}$/0.1ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥4.0 $\log_{10}$	≥4.0 $\log_{10}$	≥4.0 $\log_{10}$	

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, Maquat 710-HF, as a non-food contact surfaces foam sanitizer against the following microorganisms on hard, non-porous surfaces, in the presence of a 50% organic soil load (fetal bovine serum) against the following microorganisms for a contact time of 5 minutes at a 1:256 dilution:

Enterobacter aerogenes	MRID No. 471264-01
Listeria monocytogenes	MRID No. 471264-02
Staphylococcus aureus	MRID No. 471264-03

2. The submitted efficacy data (MRID No. 471393-01) **support** the use of the product, Maquat 710-HF, as a foam sanitizer for floor drains in food processing facilities (vertical surfaces) against the following microorganisms on hard, non-porous surfaces, in the presence of a 50% organic soil load (fetal bovine serum) against the following microorganisms for a contact time of 5 minutes at a 1:256 dilution:

Enterobacter aerogenes
Listeria monocytogenes
Staphylococcus aureus

3. The submitted efficacy data **support** the use of the product, Maquat 710-HF, as a disinfectant with virucidal activity on non-porous, non-food contact surfaces in the presence of a 5% organic soil load (fetal bovine serum), at room temperature, against the following microorganisms for a contact time of 10 minutes at a 1:128 dilution:

Newcastle disease virus	MRID No. 471264-05
Respiratory & Reproductive Syndrome virus	MRID No. 471264-06
Porcine Rotavirus	MRID No. 471264-07
Avian Influenza A virus	MRID No. 471264-08
Avian Reovirus	MRID No. 471264-09
Infectious Laryngotracheitis	MRID No. 471264-10
Avian Adenovirus	MRID No. 471264-11
Vesicular Stomatitis	MRID No. 471264-12
Pseudorabies	MRID No. 471264-13
Swine Influenza A	MRID No. 471264-14

4. The applicant **did not submit data to support** virucidal claims against **Infectious Bronchitis virus** and **Transmissible Gastroenteritis virus.**

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Maquat 710-HF, is an effective foam sanitizer for use on hard, non-porous, non-food contact surfaces against *Enterobacter aerogenes, Listeria monocytogenes,* and *Staphylococcus aureus,* when used at a 1:256 dilution in the presence of 50% serum for a contact time of 5 minutes, are **supported** by the applicant's data.

2. The proposed label claims that the product, Maquat 710-HF, is an effective foam sanitizer for floor drains in food processing facilities, against *Enterobacter aerogenes, Listeria monocytogenes,* and *Staphylococcus aureus,* when used at a 1:256 dilution in the presence of 50% serum for a contact time of 5 minutes, are **supported** by the applicant's data.

3. The proposed label claims that the product, Maquat 710-HF, is an effective virucidal for use on hard, non-porous, non-food contact surfaces against the following microorganisms when used in the presence of 5% organic soil, at room temperature, for a contact time of 10 minute at a 1:128 dilution:

Newcastle disease virus
Respiratory & Reproductive Syndrome virus
Porcine Rotavirus
Avian Influenza A virus
Avian Reovirus
Infectious Laryngotracheitis
Avian Adenovirus
Vesicular Stomatitis
Pseudorabies
Swine Influenza A

These claims are **supported** the applicant's data.

4. The proposed label claims that the product, Maquat 710-HF, is an effective virucidal for use on hard, non-porous, non-food contact surfaces against **Infectious Bronchitis virus** (IBV) and **Transmissible Gastroenteritis virus** (TGE, TGEV, also known as the Porcine Respiratory Coronavirus (PRCV)), when used in the presence of 5% organic soil, at room temperature, for a contact time of 10 minute at a 1:128 dilution, **are not supported by applicant data.** The applicant must remove **Infectious Bronchitis virus** and **Transmissible Gastroenteritis virus** from the list of viruses on the proposed label. **Studies must be submitted on these viruses.**

5. The applicant must add references to microorganisms (ATCC numbers) when applicable.

6. The proposed label directions for foam sanitization of floor drains in food processing facilities are acceptable and consistent with the Agency recommendations during meetings.